IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Group Art Unit 3732	:	PATENT APPLICATION
Examiner David A. Bonderer	:	
In re application of	:	PATELLA REPLACEMENT APPARATUS
ROBERT S. SUPINSKI	:	
Serial No. 10/007,812	:	
Filed November 8, 2001	:	

DECLARATION OF DR. ROBERT SUPINSKI UNDER 37 C.F.R. § 1.131

I, Robert Supinski, am the inventor of the patella replacement apparatus that is disclosed and claimed in the above-titled application. I am an orthopedic surgeon and have been performing orthopedic surgery since 1985.

In 1989 I conceived of a patella replacement device that could be used in repairing or replacing the destroyed natural patella of a patient. This device has two hemispherical parts and an annular ring, all fabricated from a biocompatible material. At that time I conceived that the ring and one hemispherical member would be a biocompatible metal such as titanium and the other hemispherical member would be plastic, particularly polyethylene. Posts provided on one member would fit into holes in the other member.

I made my first drawing of this patella replacement device in the fall of 1989. I am unable to locate that first drawing and believe it to have been destroyed.

On or about February 8, 1990, I disclosed my idea to Gregory Gray, a biomechanical engineer, in confidence. I asked Mr. Gray to assist me in developing a prototype of this device.

Mr. Gray sent me a letter dated February 14, 1990, which makes reference to that discussion. That letter is attached as Exhibit I.

During February and March of 1990, I had several discussions with Mr. Gray about creating a prototype of the patella replacement device. On March 15, 1990, I wrote a recap of one discussion that we had on March 7, 1990, about the prototype. A copy of those notes is attached as Exhibit II.

On or about March 7, 1990, I conceived that a better patella replacement device could be made by coating one or both hemispherical components with hydroxyapatite to provide a porous structure into which bone and soft tissue can grow. This concept is shown in the drawing contained in my notes marked as Exhibit II. Therefore, I worked with people at Dow Custom Products to have a drawing and prototype of the device made. At my direction a formal drawing was prepared by Mr. Gray of Dow Custom Products from my hand sketch and other information that I provided. The drawing was made on or about March 14, 1990. A copy of the March 14, 1990, drawing and cover letter from Mr. Gray is attached as Exhibit III.

During March, 1990, Mr. Gray was also working on making a prototype of my patella replacement device. I understand that this prototype was completed on March 15, 1990. This was the first prototype of my patella replacement device. The drawing in Exhibit III is the earliest drawing of my invention that I have been able to locate.

On August 21, 1990, I implanted the prototype device in a patient. Although I then believed that this device would work, it was necessary to implant the device in a patient and chart his progress before the product would be accepted by the medical community. Attached as Exhibit IV is a report of the surgery during which my patella replacement device was implanted. The patient's name has been redacted from the report. Following surgery I examined the patient

at regular intervals. The patient was able to resume normal activities indicating that the patella replacement was successful.

In May of 1992 I had a patella replacement device with a hydroxyapatite coating made for another one of my patients. I implanted that device in the patient on May 12, 1992, and examined the patent at intervals after surgery. The patient was able to resume normal activities and be pain free. A second operative procedure was performed at a later date and the device was inspected and found to be functioning well. Attached as Exhibit V and Exhibit VI are the operative reports dated May 12, 1992, and November 12, 1998. The patient's name has been redacted from the reports. Subsequently, I implanted other prototypes in other patients. All were able to regain improved or nearly complete function of the knee joint and suffered no discomfort after the healing.

On or about November 12, 1998, I realized that the annular ring was not necessary and indeed could cut through the prosthesis or surrounding soft tissue. Therefore, I worked with the people in the Custom Engineering Department at Biomet to have a drawing and prototype made. Attached as Exhibits VII and VIII is a hand drawing that I made of this device on January 26, 2001, and a subsequent formal drawing made by Biomet on February 9, 2001.

In July, 2001, I spoke to my patent attorney about obtaining patent protection for the various embodiments of my patella replacement device. This resulted in the preparation and filing of the present application.

I declare that the foregoing is true and correct, that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such

willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: January 2, 2004

Dr. Robert Supinski

DOW CORNING WRIGHT
P.O. BOX 100 • ARLINGTON, TN 38002

February 14, 1990

Robert Supinski, M.D.
Charles Cole Medical Ctr.
Route #6
Coudersport, PA 16915

Dear Dr. Supinski:

It was certainly a pleasure to have the opportunity to meet with you and discuss your many good ideas at the Academy Meeting this year. We appreciate you bringing these ideas to us and certainly look forward to working with you this year and for years to come. We will relay your ideas to our superiors and see where we can take them.

We thoroughly enjoyed the opportunity to both socialize and discuss the business issues. We will be contacting you in the near future regarding the specific patient custom prosthesis which we are currently redesigning. Say hello to Beth for us and if there is anything else that we can do, please do not hesitate to call.

Sincerely,

Gregory A. Gray
Sr. Custom and Revision
Products Engineer

Marc Richelsoph
Custom Products Engineer

cc: Tom Chesley
Fred Skilton

3-15-90

Recap of discussion with

Greg Craig D.C.w. from 3-7-90

as per our Earlier discussions & the

drawing I gave to Greg in New orleans

at dinner the patella needs

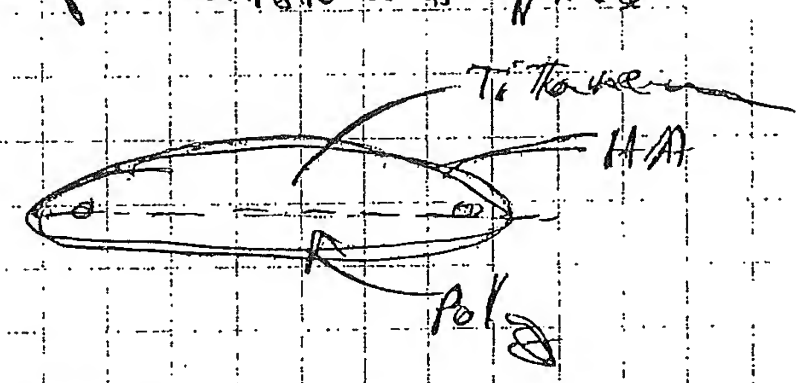
to be thicker 18 + 24 mm. 1st design

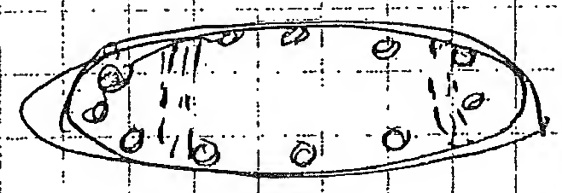
Ti foreun + HA coated. was too thin

2 holes for peripheral + transverse

Holes for Attachment with co

Dacron tape distall + prox





Greg will draw plans & send

for

would not consider dome for any

other brand

Still awaiting disclosure forms

for shoulders

DOW CORNING WRIGHT
P.O. BOX 100 • ARLINGTON, TN 38002

March 14, 1990

Robert Supinski, M.D.
Charles Cole Medical Center
Route 6
Coudersport, PA 16915

Dear Dr. Supinski:

Enclosed is a print depicting the revised design of your patellectomy patella. As requested the overall thickness of this design is 24mm. The diameter is 43.7mm as was the previous design. I did not increase this dimension because a knee morphology study showed the length and width of the average patella to be 32.3mm and 43.0mm respectively. Transverse and circumferential holes are included for attachment of the soft tissue.

Please review this print and give me a call to discuss the design in more detail. If you would like to see changes made to the design please sketch them on the print and fax them to me at (901) 867-3535 so that I can review your sketch prior to discussing the design changes. As a reminder my number is 800-238-7188 extension 560. I look forward to hearing from you soon.

Sincerely,

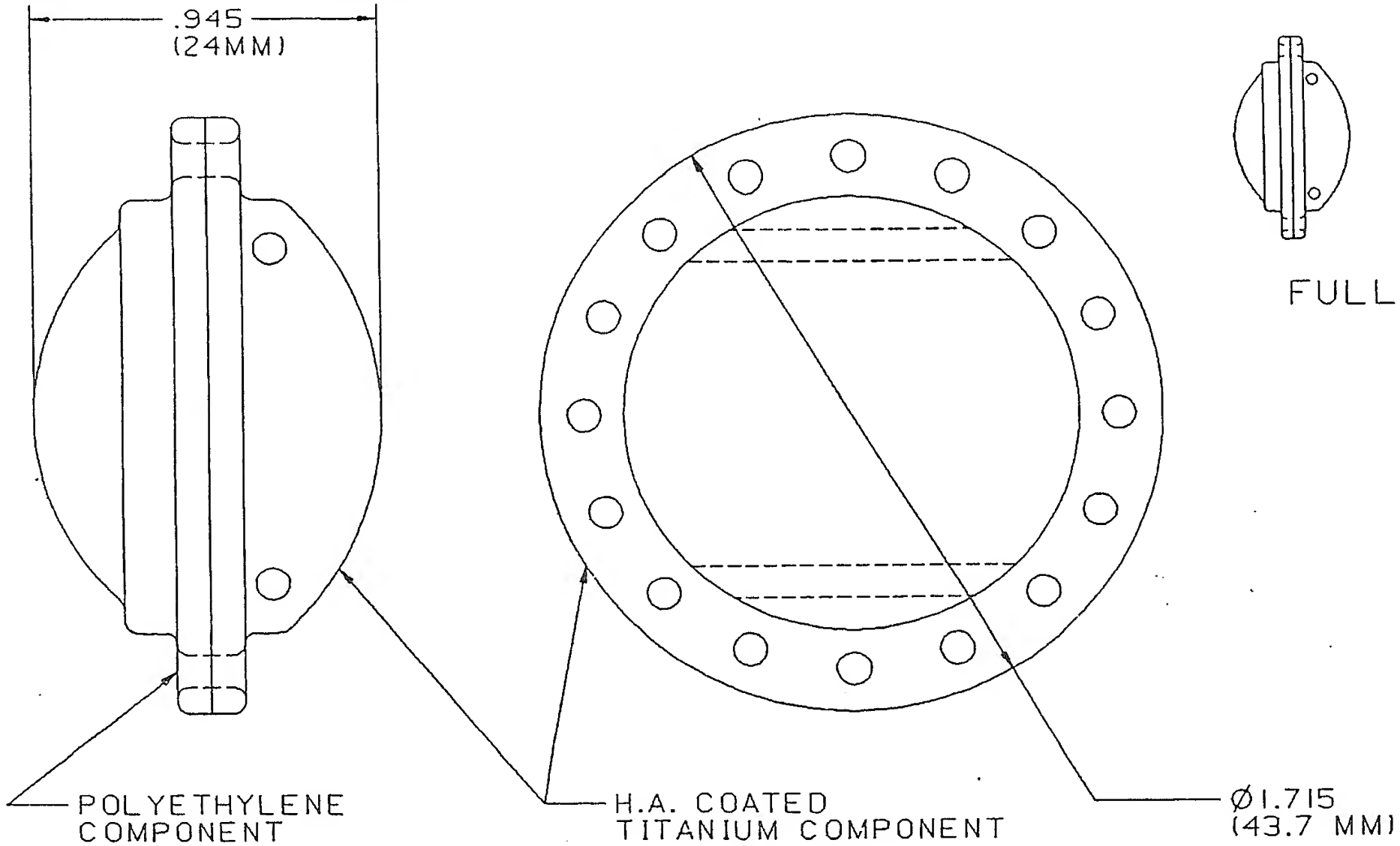
Gregory A. Gray
Sr. Custom and Revision
Products Engineer

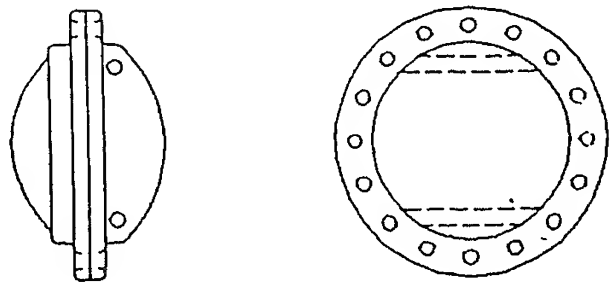
cc: Tom Chesley

DCW CUSTOM PRODUCT

DESIGN ENGINEER: GREG GRAY

PHONE: 1-800-238-7188 EXT. 560





FULL SCALE

PATIENT : [redacted]

PHYSICIAN : ROBERT SUPINSKI

SCALE : 3:1 / FULL

(SIGNATURE)
PHYSICIAN APPROVAL

DOW CORNING
WRIGHT

[redacted] 314

D: 8/22/90
T: 8/23/90 csm

DATE OF OPERATION: 8/21/90.
SURGEON: R. S. SUPINSKI, M.D.
ASSISTANT: M. B. CRUZ, M.D.

PREOPERATIVE DIAGNOSIS: FAILED TOTAL KNEE REPLACEMENT, RIGHT KNEE.

POSTOPERATIVE DIAGNOSIS: FAILED TOTAL KNEE REPLACEMENT, RIGHT KNEE.

OPERATION: REVISION OF TIBIAL COMPONENT TO A CUSTOM TIBIAL COMPONENT WITH A 15 MM. TIBIAL BUILD-UP, 20 MM. POLYETHYLENE INSERT AND CUSTOM PATELLAR COMPONENT.

INDICATIONS FOR SURGERY: This WM had undergone a revision after a failed total knee replacement. He did reasonably well with the exception of extensor lag due to the fact that his patella had been lost at the time of his revision due to severe bone loss and also he had no pain, but he did have dislocation of his prosthesis due to subsidence of the tibial component. It was decided that he should have a cemented stemmed custom component as well as a custom patellar component with a titanium metal backed porous coated prosthesis and hydroxyapatite coating.

SURGICAL FINDINGS: The patient was found to have subsidence of the tibial component and attenuation of the patellar quadriceps tendon at the area of the patellectomy from his prior surgery.

OPERATIVE PROCEDURE: The patient was identified and following a spinal anesthetic, his right leg was prepped with a Betadine scrub and solution and draped in the sterile orthopedic fashion. A longitudina incision was made over his old incision. This was carried down through the subcutaneous tissue. The tourniquet had been inflated to 300 mm. of mercury after exsanguination with an Esmarch. The patellar tendon was identified with its attenuated central portion where the patellectomy had been carried out and it was divided in that area at the junction of the quadriceps tendon with this attenuated scar tissue. This was turned down and attention was turned to the

Patient Indentification

[redacted]

(CONTINUED)

OPERATIVE PROCEDURE CONTINUED:
tibial plateau. The old polyethylene insert was removed, the screws were removed and the Whitesides base was removed. The tibia was prepared by sawing about 2 mm. of bone from it, planing it to make it level, inserting a bone plug, irrigating and drying the base. Methyl methacrylate cement was mixed and the permanent prosthesis was impacted with a 6 inch pin base and held after the methyl methacrylate had been allowed to harden with 1.2 grams of Tobramycin. Extraneous cement was removed, trial components were selected and a 20 mm. insert was selected. The permanent polyethylene insert was then impacted into place. The knee was run through a range of motion and found to have excellent stability medially and laterally, anteriorly and posteriorly. There was no tendency for dislocation even when the patient was in flexion.

Next the custom patella component was applied over the area of its anatomic position with the leg in extension and using #5 Ethibond sutures, the component was sown to the quadriceps tendons. A horizontal mattress suture through the quadriceps tendon was then used to attach it to the patellar tendon in a shortened position. Multiple sutures were placed through the periphery of the custom patella to allow for anchoring of the patella in place. Longitudinal sutures that ran through the patella into both quadriceps and the patellar tendon were used to re-enforce this area. The quadriceps and patellar tendons were oversown with multiple horizontal mattress sutures at the area of the shortening. A lateral retinacular release had been carried out and there was excellent alignment. With the leg at rest without any tension, the knee was able to drop to approximately 45-50 degrees of flexion.

Once the procedure was completed, the electric stimulator was used to show that the quadriceps could contract and partially extend the knee to try and assess stability and ability to extend the knee.

The medial incision which was left was sown with a running and interrupted suture of #1 PDS. A drain was inserted exiting through the lateral aspect of the thigh. The subcutaneous tissue was closed with 2-0 Vicryl in a running fashion and the skin was closed with staples. A sterile Jones dressing was applied, tourniquet was released at 120 minutes and the patient was taken to the Recovery Room in satisfactory condition.

R. S. SUPINSKI, M.D.

, M.D.

cc: RSS, MBC

[redacted]

[redacted]

[redacted] 310
5/13/92
5/14/92 csm

DATE OF OPERATION: 5/12/92.
SURGEON: R. S. SUPINSKI, M.D.
ASSISTANT: M. H. SHELLEY, M.D.

PREOPERATIVE DIAGNOSIS: FAILED TOTAL KNEE REPLACEMENT, LEFT KNEE.

POSTOPERATIVE DIAGNOSIS: FAILED TOTAL KNEE REPLACEEMNT, LEFT KNEE.

OPERATION: TOTAL KNEE REVISION, LEFT KNEE WITH A CUSTOM PATELLAR COMPONENT.

INDICATIONS FOR SURGERY: This patient had undergone a total knee replacement in 1983 which was revised in 1984 to a cemented total knee replacement. She did well until the past 6 months when she developed increasing pain in her left knee. Bone scanning suggested loosening of her total knee replacement. She had crepitus and griting of her patella with any motion and was tender beneath her patella. It was decided that she would benefit from a revision of her total knee replacement. Because the patellar prosthesis was loose, it was decided that a custom implant should be available and a custom total knee patellar prosthesis was designed -- native titanium with a porous coating and hydroxyapatite coating on top of that.

OPERATIVE PROCEDURE: The patient was identified and following a spinal anesthestic, the left knee was prepped with a Betadine scrub and solution and draped in the sterile orthopedic fashion. It was exsanguinated with an Esmarch and the tourniquet was inflated to 300 mm. of mercury. A longitudinal incision was made along her old scar. This was carried down through the subcutaneous tissue to the extensor retinaculum. Ethibond sutures were identified and these were removed with the scissors and forceps. The extensor retinaculum was opened in a median parapatellar approach. The patella was everted, the knee was flexed, granulation tissue was removed. The osteotome was then used to loosen the cement bone interface around the

OPERATIVE PROCEDURE CONTINUED:
femoral component and the impactor was used to disimpact the femoral component. The osteotomes and bone cement removal instruments were then used to remove the cement from the femoral component and a silastic bone plug was identified and removed. The osteotomes were then used to loosen the cement beneath the tibial component. The tibial component was extracted and there was found to be obvious loosening of the cement and all cement was removed with the cement removal instruments. Next, the patellar component was easily removed and there was found to be a cystic area of eroded bone beneath that and there was severe erosion of the bone with only a very thin cortical shell remaining. The knee was irrigated with the water pik copiously. The bone plug was inserted into the femoral canal and a bone plug was inserted into the tibial canal. Methyl methacrylate cement was mixed after the bone had been irrigated with the water pik and dried. It was applied to the tibial surface and a Whitesides III tibial component was impacted into place with methyl methacrylate cement. Cement was then applied to the femoral component and a full built Whitesides III revision stemmed femoral component was inserted and impacted into place and excessive methyl methacrylate cement was removed. It should be noted that prior to insertion, trial components were used to size the implants and the cutting instruments were then used to shape the femur to receive this and to also level the tibia using the intramedullary guide system. A 25 mm. Polyethylene insert with a large stemmed posterior stabilized design was selected. This was impacted into place. The knee was held in extension until the cement had hardened. The patella was found to have extremely thin cortices and would not support a cemented prosthesis; therefore, a custom component was then sown into place after the remaining bone had been shaped to receive this. The knee was run through a range of motion, flexion and extension and had a full range of motion with no tendency for subluxation of the patella. The knee was irrigated with the water pik. A drain was inserted exiting through the lateral aspect of the thigh. The extensor retinaculum was closed with a running and interrupted suture of #1 PDS. The patellar component had been sown in with interrupted sutures of 0 Vicryl and #1 PDS. The subcutaneous tissue was closed with 2-0 Vicryl in a running fashion and the skin was closed with staples.

A sterile dressing was applied and the patient was taken to the Recovery Room in satisfactory condition.

_____ M.D.
R. S. SUPINSKI, M.D. cc: RSS, MHS

OPERATIVE REPORT

DATE OF OPERATION: 11/12/98

PREOPERATIVE DIAGNOSIS: FAILED TOTAL KNEE REPLACEMENT, LEFT KNEE.

POSTOPERATIVE DIAGNOSIS: FAILED TOTAL KNEE REPLACEMENT, LEFT KNEE.

OPERATIVE PROCEDURE: REVISION LEFT TOTAL KNEE REPLACEMENT.

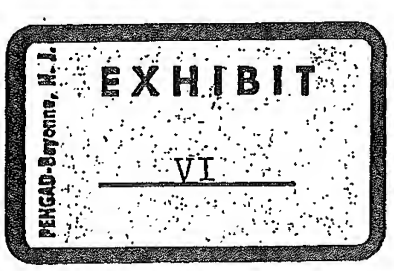
SURGEON: R.S. SUPINSKI, MD

INDICATIONS: This patient had significant pain and discomfort in her left knee. X-rays and bone scanning showed loosening of her total knee replacement which had been revised previously. A decision was made to proceed with revision.

FINDINGS AT THE TIME OF SURGERY: Loose femoral component, loose tibial component and intact patellar component.

OPERATIVE PROCEDURE: The patient was identified and following a spinal anesthetic, the left knee was prepped with Betadine DuraPrep solution and draped in sterile orthopedic fashion. A longitudinal incision was made over the anterior aspect of the knee and was carried down through the subcutaneous tissue. The extensor retinaculum was opened in a median parapatellar vastus medialis splitting incision. The patella was everted. The knee was flexed. Granulation tissue and synovitis was then excised. The polyethylene line was disimpacted. The femoral component was loosened with the osteotomes and the femoral component was disimpacted, removing most of the cement from the stem along with it. The tibial component was easily disimpacted, removing most of the cement with it. Additional cement was removed from the tibial shaft as well as the femoral shaft, using the cement removal instruments. All granulation tissue was removed with the curet and the waterpick and the saw was used judiciously to freshen surfaces.

A medium tibial component with 16 mm tibial augmentation blocks were then selected with a 150 mm tibial stem. A medium femoral component with a 150 x 14 mm femoral stem was selected and a 12 mm polyethylene insert was selected. With this, the knee had good stability and a full range of motion. It should be noted that a prior patellar component, which was a custom component was left in place as the patient did not have a patella and this domed patella was a polyethylene titanium hydroxyapatite (HA) composite which had grown into the soft tissue and still had no signs of significant wear and had good stability. The trial components were removed.



The knee was then irrigated with the waterpick and dried. Methyl methacrylate cement was mixed and the tibial augmentation blocks were cemented to the tibial tray with a 150 mm cylindrical stem impacted. The femoral component with 8 mm distal and posterior augmentations with a 150 x 14 mm stem in place was fashioned with the femoral augmentation blocks being cemented into place. In all the cement used, 1.2 grams of Tobramycin per batch was used. After the augmentation block had been cemented into place, the tibial stem was inserted partially and Osteoset granules were then placed round all areas of osteolysis to fill the tibial defect. Then, methyl methacrylate cement was applied over the tibial surface and the tibial component was impacted completely. All excessive cement was removed. In a similar fashion, the femora component was impacted into place and Osteoset graft material was then inserted along the shaft to fill in all areas of osteolysis and methyl methacrylate cement was applied over the femoral surfaces and a Performance CCK prosthesis was then impacted into place and all excessive cement was removed. The knee was held in extension with a 12 mm polyethylene insert. Once the cement had hardened the permanent 12 mm polyethylene insert was inserted with a retaining screw. The knee was then once again irrigated with the waterpick.

The extensor retinaculum was closed with a running interrupted suture of #1 PDS. The subcutaneous tissue was closed with 2-0 Vicryl in running fashion. The skin was closed with staples. A sterile dressing was applied.

The patient was taken to the Recovery Room in satisfactory condition.

Robert S. Supinski, MD

cc: RSS

D: 11/13/98 1458
T: 11/16/98 1917 MT

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U#: M000046770 A#: V00090040411
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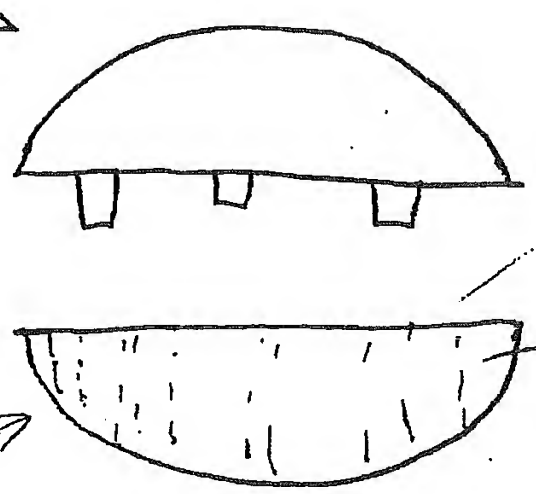
ADM IN 0402-D 11/12/98
Supinski,Robert S.

CHARLES COLE MEMORIAL HOSPITAL
Coudersport, PA

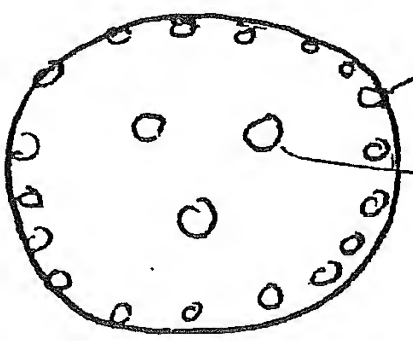
1-26-01

Genesee Regional Orthopedics & Sports Medicine
Robert S. Supinski M.D., F.A.C.S.
Charles M. Livingston RPA-C., ATC.
111 Clara Barton Street
Dansville, New York 14437
716 335-9360 • Fax: (716) 335-9436

All Poly Patellar



Plasma spray only for cement Bonding



R Supinski MD

PT: [redacted]
DR: SUPINSKI
X-9420
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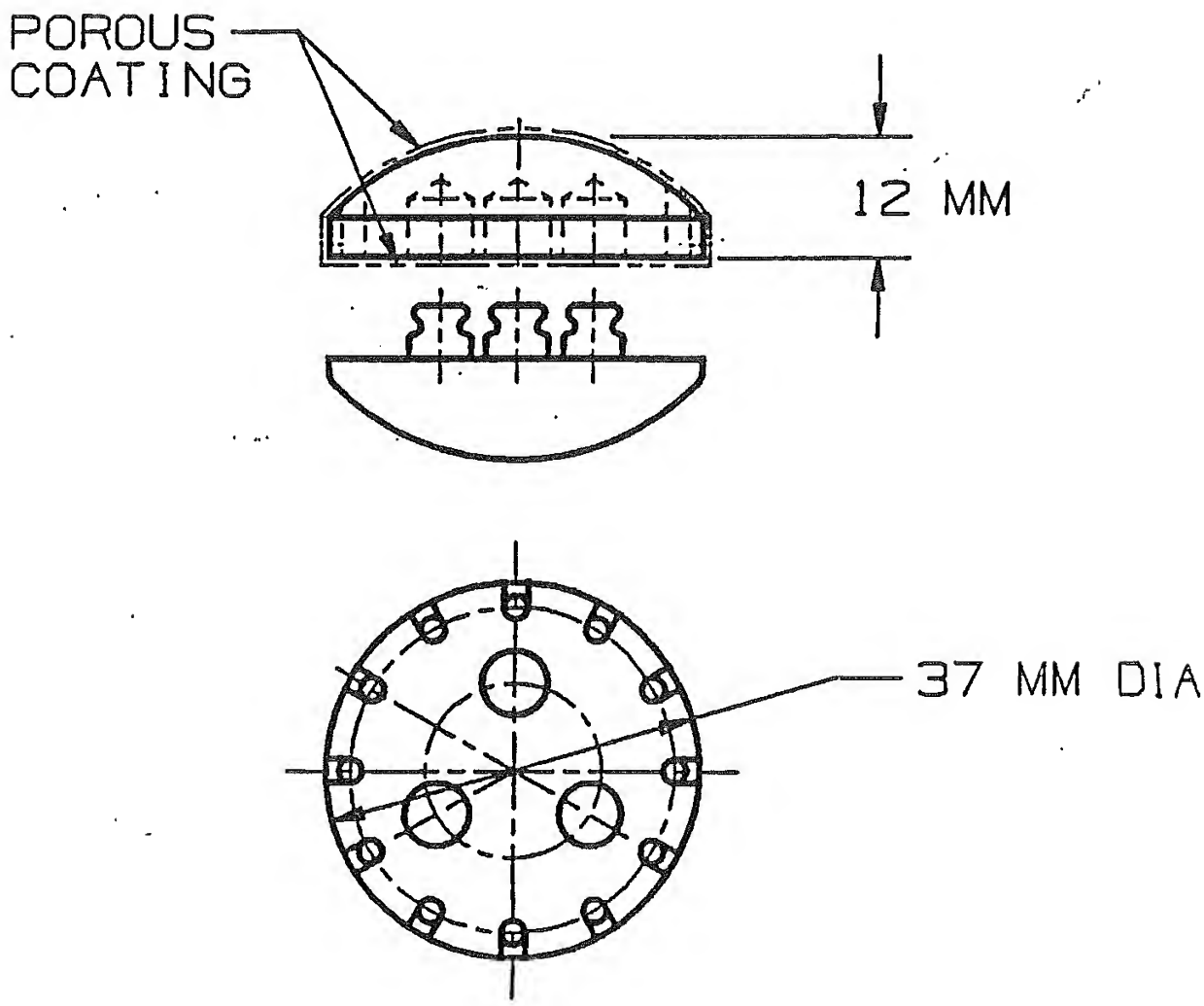

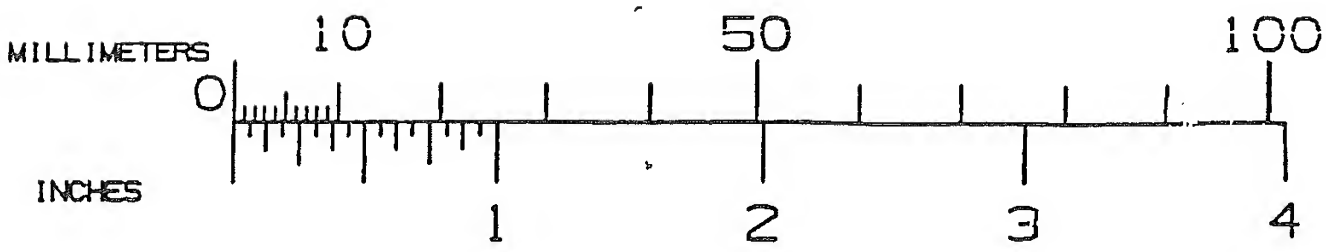

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